

A Study of the Effects on Bacteremia and Sharps Injury Rates after Introduction of an Advanced Luer Activated Device (LAD) for Intravascular Access in a Large Hospital Setting

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ABSTRACT

BACKGROUND: Over the last several years, reports from several healthcare institutions have been published indicating increased rates of bacteremias associated with the use of a variety of different LADs. Factors attributed as potential causes of device-related infections include adherence to procedure, aseptic device management, and product design. In order to address incidents of sharps injuries, the Infection Control, Products Evaluation & Standardization, and Safety Committee undertook a detailed review of an advanced positive displacement device that incorporated several risk reducing design features: smooth, flat luer surface which minimizes bacterial accumulating points; no interstitial space which reduces risk of bacterial growth; dual seal design; positive fluid pulse which assists in reducing occlusion; high-flow rates. A study was designed to determine the effect of this new device on rates of bacteremia and sharps injuries when used with peripheral IV (PIV) catheters and central lines (CL).

METHODS: Subjects in the study included all adult patients who had a peripheral intravascular extension set or central line placed at the institution after admission for a period of >1 day. Group I (6/1/06-8/31/06) patients had split septum devices (SSD) in place (INTERLINK, Baxter Healthcare, Round Lake, IL). An extensive education program for nurses, physicians, anesthesiologists, and ancillary workers was conducted focusing on safety, proper maintenance procedures, and antiseptic procedure for wiping the luer surface. Group II (9/1/06-11/30/06) patients had a positive displacement LAD placed (FLOLINK, Baxter Healthcare, Round Lake, IL.) PIVs continued to be flushed with saline. Flush procedures for CLs were changed from heparin to saline during this period. No other revisions in dressing types, skin antisepsis, dressing time changes, antiseptic wiping with 70% alcohol, IV administration set and LAD replacement (q4 days), flush times (q8h for dormant lines; flush at medication administration for intermittent lines) or other components in peripheral or central line devices were made during the two study periods.

RESULTS: Observation sessions (n=105) to verify compliance with antiseptic protocol were conducted over the two study periods. Compliance was calculated to be 98.1% (103/105). BSI rates for patients with peripheral lines were 0.17 per 1000 catheter days (CD) with SSDs

and 0.14 per 1000 CDs in patients with LADs. For patients with central lines, the rates were 1.16 in the SSD group and 1.15 in the LAD group. No statistical differences in infection rates were found between the two groups for either type of line. Sharps injuries related to IV port access were reduced from four during the Group I study period, to zero during the Group II period.

CONCLUSIONS: The results of this study suggests that use of an advanced LAD device in coordination with adherence to proper infection control practice does not contribute to increases in either BSI rates or sharps injuries.

There are no financial disclosures for this study

OVERVIEW

The use of modern intravenous devices has contributed significantly to the provision of life-saving medical care. However, the delivery of needed fluids, antibiotics, nutritional elements, and other drugs through such devices as dialysis and triple-lumen catheters, peripherally-inserted central lines, and peripheral lines, is not risk free. It is estimated that central venous catheters alone account for more than 250,000 bloodstream infections (BSIs) each year in the United States. The pathogenesis of such infections has been closely studied. (1,2) BSI may occur as a consequence of bacterial colonization of the skin surrounding the insertion site, contamination of catheter hubs or ports, contamination of intravenous fluid, or as a secondary occurrence from a remote bodily site. Bacterial colonization at the hub/port sites of central venous catheters has been shown to be the source of up to 12% of the total associated BSIs. (1)

In response to national directives from the Occupational Safety and Health Administration (OSHA) on reducing sharps injuries to healthcare workers, (3,4) medical institutions have introduced a variety of safety devices, including needleless luer-activated devices (LADs) for use on intravascular catheters and administration lines. Reports indicate that when under-reporting of sharps injuries (SIs) is taken into account, the total annual number of SIs may well be in excess of 576,000. (5) Detailed analysis of SIs collected via the National Surveillance System for Health Care Workers (NaSH) and other reports, reveals that 6% of SIs occur during intravenous access. (5)

Although LADs were introduced in large part to reduce SIs among healthcare workers, these devices were soon to be associated with increasing rates of bacteremia. Numerous reports have been published indicating outbreaks of bloodstream infection in periods after the implementation of an LAD. (6-19) The BSIs in populations using LADs were diverse, occurring in such settings as adult and pediatric intensive care units, long term care, and home care.

In light of these findings, healthcare institutions and services are finding the decision to use LADs more difficult: will decreased SI rates among employees be "offset" by increased infection events among patients? The purpose of this study is to determine the effect of implementing an advanced design LAD on SI and BSI events.

METHODS

Setting and Study Groups

The Brookdale University Hospital & Medical Center (BUHMC) is a 427-bed regional tertiary care center that includes a Level I Trauma program located in Brooklyn, New York. The BUHMC Emergency Department sees more than 120,000 patients per year. Admissions to the medical center exceed 28,000 per year.

A decision to investigate the use of LADs at BUHMC was made in reaction to injuries identified following a review of system-wide SIs. Data indicated that nurses in particular were accessing split septum IV ports during such procedures as delivery of medications from a vial through the port using a syringe with needle. National directives required the hospital to implement safer systems that reduced the risk of SIs to HCWs. (4) Meetings organized by Infection Control included members of risk management, materials management, nurse management and education, emergency department, peri-operative department, critical care, and pharmacy. Various vendors presented information on their LAD products.

Hospital management recommended approval of a LAD trial with a designated period whereby bacteremia rates would be monitored. Subjects in the study included patients >18 years old who had a PIV catheter and extension set or a central line placed at BUHMC after admission and whose duration of catheterization exceeded 24 hours. Patients were located in one of four critical care units or in

one of the five medical-surgical care units within BUHMC. Group I consisted of adult patients admitted between 6/1/06 and 8/31/06 that had either a PIVs or CLs with a SSD attached (INTERLINK, Baxter Healthcare, Round Lake, IL). Group II patients (9/1/06 – 11/30/06) had positive displacement LADs attached to either a PIV or CL (FLOLINK, Baxter Healthcare, Round Lake, IL). Vendor clinicians provided inservice education to all end users emphasizing recommended use and maintenance as well as reviewing hospital intravascular protocols.

Intravascular Protocols

Intravascular protocols used during both study periods are as follows: PIV catheters are replaced every four days or as needed; central lines are replaced when clinically necessary; dressings for all intravascular devices are replaced at the time of catheter replacement or as needed; transparent, high-permeability dressings are used for all peripheral and central catheter insertion sites; administration sets used with PIVs are replaced at the time of catheter change while sets used for CL infusion are replaced every four days or at the time of catheter replacement; 70% alcohol-2% chlorhexidine skin antisepsis; surfaces of SSDs and LADs wiped with an alcohol pad prior to each access; both SSDs and LADs are replaced every four days. Flush protocols included every 8 hours for dormant lines and at the time of medication administration for intermittent lines. Flush solutions for CLs were changed from heparin in Group I to saline in Group II (manufacturer's recommendation). PIVs continued to be flushed with saline in both groups.

Registered nurses or physicians insert peripheral intravenous catheters. Central venous catheters include triple-lumen central lines, hemodialysis catheters, and peripherally inserted central catheters (PICCs). Credentialed attendings or residents place triple lumen central venous catheters. Dual lumen hemodialysis catheters are placed by experienced physicians or dialysis nurses. Trained registered nurses, surgeons, or Invasive Radiology physicians insert PICCs. Measures to prevent central line-associated bacteremia have been implemented at BUHMC since 2000 and include the use of maximal sterile barriers, large drapes, 2% chlorhexidine skin antisepsis, use of an insertion checklist, monitoring of site dressings, and daily assessment of line necessity.



Definition of a Bloodstream Infection

A patient was considered to have a primary BSI when the patient had either [1] a recognized pathogen cultured from one or more blood cultures and the organism was not related to an infection at another site, or [2] the patient had either fever ($>38^{\circ}$), chills, or hypotension and the signs and symptoms and positive lab results were not related to an infection at another site. Common skin contaminant had to have been cultured from two or more blood cultures drawn on separate occasions or from one blood culture if there was evidence that the physician started appropriate antimicrobial therapy. Patients were assessed for bacteremia until discharge from the facility, expiration, or until 48 hours after removal of the device. The Assistant Director of Infection Control and two Infection Control Coordinators made determination of a BSI case.

Compliance with Surface Antisepsis

Experienced infection control coordinators (ICCs) performed a total of 105 random observations for compliance

with using alcohol for site disinfection of the tops of intravascular valves. Monitoring was incorporated into environment of care rounds. Medication nurses were not informed that such monitoring was being conducted. Compliance with the antisepsis protocol was 98.2% (54/55) during the SSD period and 98.0% (49/50) in the LAD period.

RESULTS

Table 1 summarizes the bacteremia rates for intravascular lines during the SSD and LAD periods. BSI rates for patients with peripheral lines were 0.17 per 1000 catheter days (CD) with SSDs and 0.14 per 1000 CDs in patients with LADs. For patients with central lines, the rates were 1.16 in the SSD group and 1.15 in the LAD group. At 95% confidence intervals, p values did not indicate a significant difference between the BSI rates in the SSD or LAD groups in patients with peripheral or central lines. Sharps injuries related to IV port access were reduced from four during the Group I study period, to zero during the Group II period.

Table 1. Bloodstream infection rates, SSD and LAD Periods

	Split Septum Period			Luer Activated Device Period			P value, BSI rates
	No. Patients	No. catheter days	BSI rate* (#BSI)	No. Patients	No. catheter days	BSI rate* (#BSI)	
Peripheral line	5,391	28,700	0.17 (5)	5,343	28,450	0.14 (4)	0.97
Central line	203	2,566	1.16 (3)	212	2,612	1.15 (3)	0.89

*per 1000 catheter days

Table 2 describes the microorganisms identified in the BSI cases in the study periods.

Table 2. Microorganisms in BSI cases.

	SSD period	LAD period
Peripheral lines	<i>Staphylococcus epidermidis</i> (3) <i>Enterococcus faecalis</i> (1) <i>Providencia stuartii</i> (1)	<i>Staphylococcus epidermidis</i> (1) <i>Staphylococcus aureus</i> (2) <i>Klebsiella pneumoniae</i> (1)
Central lines	<i>Acinetobacter baumannii</i> (1) <i>Candida albicans</i> (1) <i>Staphylococcus aureus</i> (1)	<i>Enterococcus faecalis</i> (1) <i>Candida albicans</i> (1) MRSA (1)

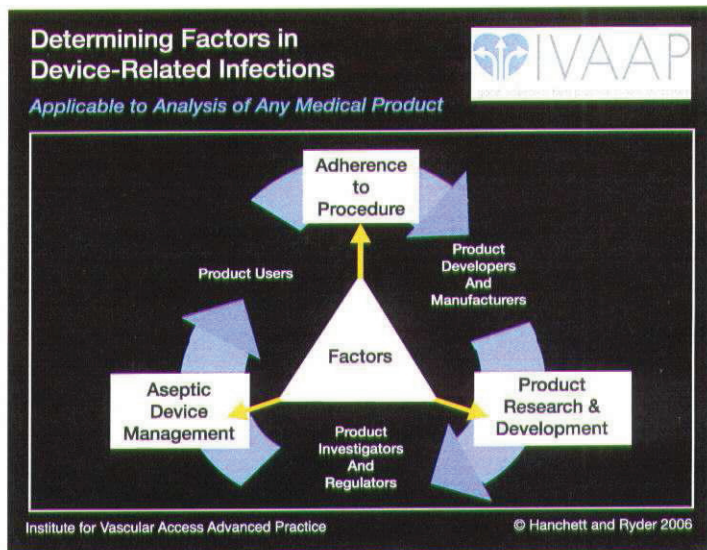
DISCUSSION

Until recently, many healthcare facilities in the United States supplied intravenous tubing connections that use beveled, hollow-bore needles to pierce the rubber membrane on catheter caps. In response to national mandates to reduce SI events among HCWs, the medical industry has produced a wide variety of needleless connectors. Although the newer designs may reduce SIs overall, the new connectors appear to be a potential source for bacterial colonization, a possible focus of biofilm formation, and eventual BSI.

Several institutions have recently reported increases in rates of BSI when conversions were made in needleless devices. Salgado and colleagues reported a BSI increase from 1.79 infections per 1000 catheter days to 5.41 when SSDs were replaced with an LAD. BSIs caused by gram-negative bacteria increased in proportion from 8% in the SSD group to 39.5% in the LAD group. (16) Similar outcomes were reported by Rupp and colleagues when a switch was made from an SSD to a positive displacement LAD (positive fluid displacement LADs are designed to prevent retrograde bloodflow into the catheter after disconnection of a luer-tip syringe). The rates of BSI among ICU/Transplant populations increased nearly three-fold (from 3.87 per 1000 catheter days to 10.43, SSD group to LAD group, respectively). In nine other inpatient settings the rate increased from 3.47 to 7.51.

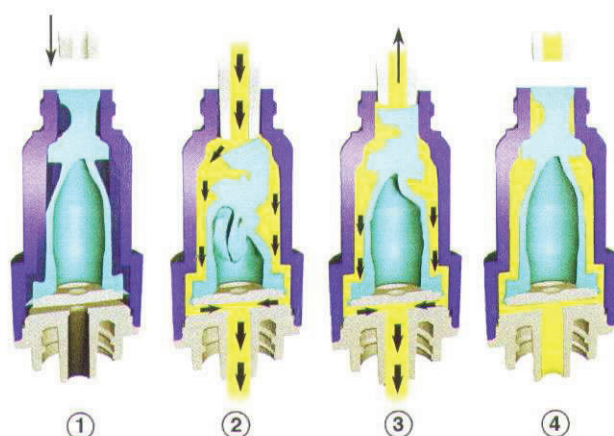
BSI rate increases have also been reported when mechanical valves without positive pressure were replaced with a device that incorporated positive pressure. Johns Hopkins Hospital indicated that rates increased by 60% among adult patients and by 80% in the pediatric population. In all these examples, rates of infection decreased after the hospitals re-instituted the original needless devices.

The reasons for the potential contamination of LADs may vary widely: lack of proper disinfection of the LAD surface prior to access, failure to correctly or completely flush the device, failure to clamp the extension set as per manufacturer's recommendations, lack of adherence to replacement protocol, device design, flow path configuration, residual fluid and displacement volumes (Figure 1).



The study summarized here attempts to determine the effects on BSI and SI rates when using an advanced LAD combined with direct observations to measure protocol compliance with surface antisepsis. Most of the reports on increasing BSI rates after implementation of an LAD did not attempt to measure nursing compliance with the use of 70% alcohol to disinfect the LAD surfaces. Contamination of catheter hubs, needleless connectors, and injection ports resulting from frequent handling by HCWs increases the risk of patient's developing intravascular-associated BSIs. (20) In this study, more than 100 procedure observations indicated that compliance with antisepsis was very high, >98%.

The LAD used in this study was reviewed by several internal committees, including the Products Evaluation & Standardization Committee, on which both Infection Control and Bio-Medical Engineering serve. Review of information on the device indicated several features which assisted in the approval process: a smooth, flat surface devoid of any significant crevices; no interstitial space; a dual seal design; a positive fluid pulse that eliminates clamping during flush procedures; and high-flow rates (Figure 2).



This study is also unique in that infection rates were determined for two different types of intravascular devices. More than 10,000 patients with peripheral IVs were prospectively followed to determine rates of BSI. The rates between the two groups, those using SSDs or LADs, did not significantly differ. The before/after PIV BSI rates could not be compared to other reports indicating increased BSI rates since rates for PIVs were not indicated. The BSI rates among 415 patients in this study with central lines using either a SSD or a LAD also did not demonstrate any statistical difference. Maragakis and colleagues at Johns Hopkins Hospital reported before/after rates of 1.50/2.40 in adult ICU patients when switched from a mechanical valve without positive pressure to one with positive pressure. (11) Although 70% alcohol was cited as being used, compliance with using this protocol was not indicated. BSI rates reported among adult patients from other institutions is summarized in Table 3, including information from hospitals summarized from recent work by Dr. W. Jarvis. (21)

Table 3. BSI Rates reported from additional hospitals converting to LADs.

Author	Location	"Before" device	BSI rate, original valve	"After" device	BSI rate, after conversion
Maragakis, 2006	All ICUs	MV, w/o PD	1.50	PDMV	2.40
Jarvis, 2006 - Hospital B - Hospital D - Hospital E	HW HW ICU	SSD SSD SSD	2.3 1.5 5.7	PDMV IC-SSD PDMV	3.5 5.1 8.5
Salgado, 2006	Long-term acute care hospital	SSD	1.79	MV	5.41
Rupp, 2006	ICU/Transplant	SSD	3.87	PDMV	10.43
	9 other inpatient units	SSD	3.47	PDMV	7.51

Rates are per 1000 catheter days
MV = mechanical valve
PD = positive displacement
HW = hospital-wide
IC = internal cannula

Recent meta-analyses of studies examining the effect of needleless mechanical valves did not lead to objections in using such devices. However, there did not appear to be sufficient evidence to justify a general usage in intravascular therapy. (22) The complexity of design appears to be associated with an increase in bacterial transfer in many of the currently manufactured mechanical valves in in-vitro testing when surface antisepsis was not used. (23). Risk at the clinical setting may be compounded by the number of accesses over in-use days, as well as the time period until the device is replaced.

CONCLUSION

The results of this study suggests that use of an advanced LAD device in coordination with adherence to proper infection control practice does not contribute to increases in either BSI rates or sharps injuries.

References

1. Safdar N, Maki DG. The pathogenesis of catheter-related bloodstream infection with noncuffed short-term central venous catheters. *Int Care Med* 2004;30:62-7.
2. Maki DG, Cobb L, Garman JK. An attachable silver-impregnated cuff for prevention of infection with central venous catheters. A prospective randomized multi-center trial. *Am J Med* 1988;85:307-14.
3. Occupational Safety and Health Administration. Bloodborne Pathogens Standard, 1991. Available at http://osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051. Accessed 5/15/07.
4. Occupational Safety and Health Administration. Federal Needlestick Safety and Prevention Act, 2001. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_cong_public_laws&docid=f:publ430.106. Accessed 5/15/07.
5. Centers for Disease Control & Prevention (CDC). Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program. February 12, 2004. Available at: <http://www.cdc.gov/sharpssafety/index.html>. Accessed 04/30/2007.
6. Danzig LE, et al. Bloodstream infections associated with a needleless intravenous infusion system in patients receiving home infusion therapy. *JANA* 1995;273:1862-4.
7. Cookson ST, et al. Increased bloodstream infection rates in surgical patients associated with variation from recommended use and care following implementation of a needleless device. *ICHE* 1998;19:23-7.
8. McDonald LC, et al. Line-associated bloodstream infections in pediatric intensive-care unit patients associated with needleless device and intermittent intravenous therapy. *ICHE* 1998;19:772-7.
9. Do AN, et al. Bloodstream infection associated with needleless device use and the importance of infection-control practices in the home health care setting. *J Infect Dis* 1999;179:442-48.
10. Hall K. Increased BSIs temporally associated with the introduction of a mechanical valve (MV) needleless device (ND). Presented at SHEA Annual Scientific Meeting, March 2004.
11. Maragakis LL, Bradley KL, Song X, et al. Increased bloodstream infection rates after the introduction of a new mechanical valve intravenous port. *Infect Control Hosp Epidemiol* 2006;27:67-70.
12. McDonald LC, Banerjee SN, Jarvis WR. Line-associated bloodstream infections in pediatric intensive care unit patients associated with a needleless device and intermittent intravenous therapy. *Infect Control Hosp Epidemiol* 1998;19:772-77.

References (continued)

13. Cookson ST, Ihrig M, O'Mara EM, et al. Increased bloodstream infection rate in surgical patients associated with variation from recommended use and care following implementation of a needleless device. *Infect Control Hosp Epidemiol* 1998;19:23-27.
14. Rupp ME, Sholtz LA, Jourdan DR, et al. Outbreak of catheter-related bloodstream infections temporally associated with a positive displacement valve. *Clin Infect Dis* 2007;44:1408-14.
15. Karchmer T, Cook E, Palavecino E, et al. Needleless valve ports may be associated with a high rate of catheter-associated bloodstream infection. Abstract presented at the SHEA Annual Scientific Meeting, April 2005.
16. Salgado CD, Chinnes L, Cantey JR, et al. Significantly increased rate of catheter-related bloodstream infections (CRBSI) associated with use of a needleless valve (NV) system in a long-term acute care (LTAC) hospital. Presented at SHEA Annual Scientific Meeting, March 2006.
17. Adams D, Karpanen T, Worthington T, et al. Infection risk associated with a closed luer access device. *J Hosp Infect* 2006;62:353-57.
18. Field K, McFarlane C, Cheng AC, et al. Incidence of catheter-related bloodstream infection among patients with a needleless, mechanical valve-based intravenous connector in an Australian hematology-oncology unit. *Infect Control Hosp Epidemiol* 2007;28:610-3.
19. Kellerman S, Shay DK, Howard J, et al. Bloodstream infection in home infusion patients: the influence of race and needleless intravascular access devices. *J Pediatr* 1996;129:711-17.
20. Menhay SZ, Maki DG. Disinfection of needleless catheter connectors and access ports with alcohol may prevent microbial entry: the promise of a novel antiseptic-barrier cap. *ICHE* 2006;27:23-7.
21. Jarvis WR. Needleless intravascular devices: when good devices go bad. APIC Webnar, July 11, 2006.
22. Niel-Weise BS, Daha TJ, Van den Brock PJ. Is there evidence for recommending needleless closed catheter access systems in guidelines? A systematic review of randomized controlled trials. *J Hosp Infect* 2006;62:406-13.
23. Ryder M, Fisher S, Hamilton G, Hamilton M, et al. Bacterial transfer through needlefree connectors: comparison of nine different devices. Abstract, SHEA Conference, 2007.